K122072
pg 1 of 2

SECTION 5
510(k) SUMMARY

510(k) SUMMARY

SEP 2 8 2012

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4872
Fax: 508-683-5939

Contact: Laurie Pannella, RAC
Regulatory Affairs Specialist
Date Prepared: July 13, 2012

2. Proposed Device:

Trade Name: WallFlex™ Biliary RX Stent System Uncovered
WallFlex™ Biliary RX Stent System Partially Covered
WallFlex™ Biliary RX Stent System Fully Covered
Classification Name: Catheter, Biliary, Diagnostic
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device:

Trade Name: WallFlex™ Biliary RX Stent System Uncovered
Manufacturer and Clearance Number: Boston Scientific Corporation, K061231, K081733
Classification Name: Catheter, Biliary, Diagnostic
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Trade Name: WallFlex™ Biliary RX Stent System Partially Covered
Manufacturer and Clearance Number: Boston Scientific Corporation, K083374
Classification Name: Catheter, Biliary, Surgical
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Trade Name: WallFlex™ Biliary RX Stent System Fully Covered
Manufacturer and Clearance Number: Boston Scientific Corporation, K083627
Classification Name: Catheter, Biliary, Surgical
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

Trade Name: WallFlex™ Biliary Transhepatic System
Manufacturer and Clearance Number: Boston Scientific Corporation, K112543
Classification Name: Catheter, Biliary, Surgical
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

4. Proposed Device Description:
The WallFlex™ Biliary RX Stent System Uncovered, WallFlex™ Biliary RX Stent System Partially Covered, and WallFlex™ Biliary RX Stent System Fully Covered consist of a flexible delivery system preloaded with a self-expanding biliary metal stent.

The stent is offered uncovered or covered. The covered stents are offered as fully covered, or partially covered with a Permalume™ stent covering. The stent wires have a radiopaque core to improve radiopacity.

The stent is preloaded onto the delivery system, which has radiopaque marker bands used to aid in imaging during deployment of the stent. The delivery system accommodates a 0.035 in (0.89 mm) guidewire.

5. Intended Use:
The WallFlex™ Biliary RX Stent System Uncovered, WallFlex™ Biliary RX Stent System Partially Covered, and WallFlex™ Biliary RX Stent System Fully Covered are indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms.

6. Technological Characteristics:
There are no differences in the technological characteristics between the proposed and predicate devices. The purpose of the this Traditional 510(k) is to request a labeling claim that the proposed WallFlex™ Biliary RX Stent System Uncovered, WallFlex™ Biliary RX Stent System Partially Covered, and WallFlex™ Biliary RX Stent System Fully Covered stents are MR Conditional safe and compatible for both 1.5 and 3.0 Tesla.

7. Performance Data:
In-vitro testing on the biliary metal stent was performed as part of the WallFlex™ Biliary Transhepatic System Tradition 510(k) submission (K112543).

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed WallFlex™ Biliary RX Stent System Uncovered, WallFlex™ Biliary RX Stent System Partially Covered, and WallFlex™ Biliary RX Stent System Fully Covered are substantially equivalent to Boston Scientific Corporation's currently marketed WallFlex™ Biliary RX Stent System (K061231, K081733, K083374, and K083627), and the WallFlex™ Biliary Transhepatic Stent System (K112543).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Laurie Pannella
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

SEP 28 2012

Re: K122072
Trade/Device Name: WallFlex™ Biliary RX Stent System Uncovered
WallFlex™ Biliary RX Stent System Partially Covered
WallFlex™ Biliary RX Stent System Fully Covered
Regulation Number: CFR 21§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: July 13, 2012
Received: July 16, 2012

Dear Ms. Pannella:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that these devices will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the devices' labeling:

> The safety and effectiveness of this device for use in the vascular system has not been established.

Furthermore, the indication for palliative treatment of biliary strictures produced by malignant neoplasms must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and permits your devices to proceed to the market. This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K122072

Device Name: WallFlex™ Biliary RX Stent System Uncovered
WallFlex™ Biliary RX Stent System Partially Covered
WallFlex™ Biliary RX Stent System Fully Covered

Indications For Use: For use in the palliative treatment of biliary strictures produced by malignant neoplasms

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122072